

§ 8.32

to resolve disputes in accordance with the objectives of the procedures in this subpart.

§ 8.32 Administrative record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

§ 8.33 Written decision.

(a) *Issuance of decision.* The reviewing official shall issue a written decision upholding or denying the suspension, proposed revocation, or adverse action. The decision will set forth the reasons for the decision and describe the basis for that decision in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of decision.* The reviewing official will attempt to issue the decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public notice and communications to the Drug Enforcement Administration (DEA).* (1) If the suspension and proposed revocation of OTP certification are upheld, the revocation of certification will become effective immediately and the public will be notified by publication of a notice in the FEDERAL REGISTER. SAMHSA will notify DEA within 5 days that the OTP's registration should be revoked.

(2) If the suspension and proposed revocation of OTP certification are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the FEDERAL REGISTER. SAMHSA will notify DEA

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within 5 days that the OTP's registration should be restored, if applicable.

§ 8.34 Court review of final administrative action; exhaustion of administrative remedies.

Before any legal action is filed in court challenging the suspension, proposed revocation, or adverse action, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under § 8.28(e) or § 8.33(a), constitutes final agency action as of the date of the decision.

PART 9—STANDARDS OF CARE FOR CHIMPANZEES HELD IN THE FEDERALLY SUPPORTED SANCTUARY SYSTEM

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- 9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.
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- 9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.
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AUTHORITY: 42 U.S.C. 216, 287a–3a.

SOURCE: 73 FR 60423, Oct. 10, 2008, unless otherwise noted.

§ 9.1 Applicability and purpose.

(a) *General.* The standards of care set forth in this part apply to the chimpanzee sanctuaries that are contracted (or subcontracted) to the Federal Government to operate the federally supported chimpanzee sanctuary system authorized by section 481C of the Public Health Service (PHS) Act, as amended (42 U.S.C. 287a–3a).

(b) *What is the purpose of the federally supported chimpanzee sanctuary system and the authority for establishing these*

standards of care regulation? The Chimpanzee Health Improvement, Maintenance, and Protection Act (Pub. L. 106-551, referred to as the “CHIMP Act” or “Chimpanzee Retirement Act”) was enacted by Congress to provide for the establishment and operation of a sanctuary system to provide lifetime care for chimpanzees that have been used, or were bred or purchased for use, in research conducted or supported by the agencies of the Federal Government, and that are determined to be no longer needed for such research. The CHIMP Act also mandates that standards of care for chimpanzees in the sanctuary shall be developed to ensure the well-being of chimpanzees and the health and safety of the chimpanzees.

(c) *To what chimpanzee sanctuaries do the standards of care in this part apply?* The standards of care set forth in this part apply to only those sanctuaries that are contracted or subcontracted to the Federal Government to operate the federally supported chimpanzee sanctuary system.

§9.2 Definitions.

As used in this part:

Adequate veterinary care means a program directed by a veterinarian qualified through training and/or experience to provide professional medical care to the chimpanzees within the Sanctuary and with the appropriate authority to provide this care. The program also provides guidance to all caregivers on all matters relating to the health and well-being of the chimpanzees.

American Zoo and Aquarium Association (AZA) means the professional society composed of individuals with various backgrounds and interests that are devoted to advancing the knowledge and understanding of zoo animals and the management of zoos in the United States.

American Zoo and Aquarium Association (AZA) Accreditation Standards are those standards developed by the AZA that are used to review, evaluate, and accredit zoos or zoological gardens. These standards cover a variety of areas including facilities, policies and procedures, training, staff qualifications, medical and animal care, husbandry and well-being procedures, and

conservation, along with other specific areas.

Animal Care and Use Committee means the Institutional Animal Care and Use Committee established under section 13(b) of the Animal Welfare Act of 1985 and the Health Research Extension Act of 1985. For the purpose of these Standards of Care, it shall consist of at least five (5) members including the Chairperson, a Doctor of Veterinary Medicine (D.V.M. or V.M.D.) knowledgeable in nonhuman primate care and diseases and with delegated program responsibility, a member not affiliated with the Sanctuary, a scientist, and a member of the animal protection community. The requirement that a member of the ACUC must be from an animal protection organization is unique to this part and is not required under the Animal Welfare Regulations or the Public Health Service Policy on the Humane Care and Use of Laboratory Animals. This Committee must be established if research as defined by the Animal Welfare Act Regulations and the Public Health Service Policy (research, teaching, testing, exhibition) is to be conducted at the sanctuary.

Animal protection organization means a nonprofit organization whose primary mission is protection of animals through positive advocacy and action.

Animal Resource Manager (or Animal Resource Supervisor) means the individual employee responsible for managing the nonprofessional staff providing care for the chimpanzees at the sanctuary. This individual may perform other duties as assigned by the Sanctuary Contractor.

Animal Welfare Act/Regulations means the Act of August 24, 1966 (Pub. L. 89-544, commonly known as the Laboratory Animal Welfare Act), as amended by the Act of December 24, 1970 (Pub. L. 91-579, the Animal Welfare Act of 1970), the Act of April 22, 1976 (Pub. L. 94-279, the Animal Welfare Act of 1976), and the Act of December 23, 1985 (Pub. L. 99-198, the Food Security Act of 1985), and as may be subsequently amended, and the United States Department of Agriculture (USDA) regulations implementing the Animal Welfare Act in title 9, chapter 1, subchapter A of the CFR.